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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,670	01/16/2002	Antonia Costa Bauza	2642-1-001	5089

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EXAMINER	
COE, SUSAN D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,670	COSTA BAUZA ET AL.	
	Examiner	Art Unit	
	Susan D. Coe	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2004 and 26 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-16* is/are pending in the application.

4a) Of the above claim(s) *8 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,9-13,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/26/03 & 6/25/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed March 26, 2004 has been received and entered.

2. Claims 11-16 have been added.

3. Claims 6-16 are currently pending.

Election/Restrictions

4. Applicant's election with traverse of wheat germ for species A in the reply filed on September 30, 2004 is acknowledged. The traversal is on the ground(s) that all of the germ flours claimed have the same technical feature in regards to phytate in the flour. This is not found persuasive because even if the flours do all contain phytate, a search of all of the species is still considered to be burdensome. Applicant claims four specific flours or any combination thereof and the broad claims encompass additional flours. A search of all of these flours would be burdensome because a search of one flour would not be coextensive with a search of the other flours.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 8 and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 30, 2004 and March 26, 2004.

6. Claims 6, 7, 9-13, and 15-16 are examined on the merits solely in regards to the elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 6, 7, 9-13, and 15-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment and reducing the occurrence of kidney stones and treating diabetes, does not reasonably provide enablement for prevention of these disorders and for treatment and prevention of any other disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant broadly claims treatment or prevention of any pathological or pre-pathological conditions derived from a phytate deficient state. As discussed below, the full definition of what conditions are encompassed by this statement is unclear. Since it is unclear exactly what conditions are considered to be derived from phytate deficient states, a person of ordinary skill in the art cannot reasonably be expected to determine if such an undefined condition is able to be treated with the germ flours claimed.

Applicant's specification links phytate deficiencies with diabetes, colon cancer, high cholesterol, and kidney stones. Each of these will be discussed in turn. Firstly, applicant is not considered to be enabled for the prevention of diabetes. Diabetes type I is a genetic disorder that can be treated but not prevented. Type II diabetes is recognized by the American Diabetic Association as potentially preventable using a combination of diet and exercise (see www.diabetes.org/diabetes-prevention/how-to-prevent-diabetes.jsp). Applicant's specification does not give any examples that show that the germ flours are able to prevent either type of diabetes. Applicant does not discuss the known means for preventing type II diabetes. Thus, applicant does not provide enough information for a person of ordinary skill in the art to determine without undue experimentation that the germ flours claimed are able to prevent diabetes.

Secondly, applicant is not considered to be enabled for the prevention or treatment of colon cancer. Treatment of cancer is well known in the art to be extremely unpredictable especially in humans. A compound that functions in vitro or in an animal model is not considered predicative of success in treatment of cancer in a human (see Gura (Science (1997), vol. 278, pp. 1041-2). Prevention of cancer is well known to difficult to predict and achieve. Applicant does not provide any evidence that the claimed germ flours are able to prevent or treat cancer. Due to the unpredictability of the prevention and treatment of cancer, a person of ordinary skill in the art would be forced to experiment unduly to determine if applicant's invention is able to function as claimed.

Thirdly, applicant is not considered enabled for prevention of high cholesterol. This is also a condition that is difficult to definitely prevent. Numerous factors contribute to the

development of high cholesterol. Individuals with low-cholesterol diets can still develop high cholesterol due to genetic disorders such as familial hypercholesterolemia (see www.emedicine.com/med/topic1072.htm). Applicant does not provide any evidence that shows that the germ flours are able to prevent high cholesterol. Thus, due to the known unpredictability of prevention of high cholesterol, applicant is not considered enable for the prevention of high cholesterol.

Finally, applicant claims prevention of kidney stones. Applicant's specification does show a reduction in the incidence of kidney stones. Art accepted means for prevention of kidney stones includes increase in water intake combined with dietary changes (see www.mayoclinic.com/invoke.cfm?id=DS00282). Applicant does not address these known methods for prevention of kidney stones. Applicant also does not provide any evidence that the claimed germ flours are able to prevent kidney stones in each and every incidence of kidney stones. Thus, since applicant does not use art accepted means for preventing kidney stones, applicant's claims are not considered to be enabled for the prevention of kidney stones. A person of ordinary skill in the art would be forced to experiment unduly to determine if the invention would function as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 6, 7, 9-13, and 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's claims are considered indefinite because the full

definition of pathological and pre-pathological conditions that are associated with phytate deficient states is unclear. Applicant does not provide a complete definition of what disease are encompassed by this phrase in the claim. In addition, applicant does not define what are considered pre-pathological states for conditions associated with phytate deficiency. Thus, since the complete definition of these term is unclear, the metes and bounds of the claims are unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 6, 7, 10-13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 4,496,606.

Applicant's claims are drawn to treating a condition associated with phytate deficiency using a food product made from wheat germ flour. Applicant's specification at page 5 defines diabetes as one such condition.

US '606 teaches a food bar composition that includes wheat germ (see claim 4). The germ itself is claimed; thus, it has been separated from the fruit. The reference teaches using the food bar to treat diabetes (see columns 1-4). The reference does not specifically teach that the treatment of diabetes is related to phytate. However, the reference teaches administering a composition that is the same as the claimed composition to the same patient as claimed, i.e. a

diabetic. Thus, the reference is considered to inherently anticipate the claimed method of treatment.

The reference also does not teach reduction in the incidence of kidney stones. However, this method is also considered to be inherently present in the teaching of the reference. Any person is at risk to get kidney stones. Thus, the food bar administered in the reference would be administered to someone at risk to get kidney stones. Therefore, the reference inherently anticipates reduction in the occurrence of kidney stones.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 6, 9, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 4,496,606.

The teaching of this reference is discussed above. However, the reference does not specifically teach using the wheat germ in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient in the food bar composition to add in order to best achieve the desired results. Thus,

absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

11. Claims 6, 7, 9-13, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 4,496,606 in view of Lieske et al. (American Journal of Physiology (1997), vol. 272, F224-33).

As discussed above, US '606 teaches a composition that contains wheat germ. However, the reference does not specifically teach that this composition is useful in treating kidney stones. Lieske teaches that wheat germ extracts are able to reduce the adherence of hydroxyapatite crystals to renal cells. This adherence is a cause of kidney stones. Thus, a person of ordinary skill in the art would reasonably expect that administering a wheat germ containing product would help treat and reduce the risk of kidney stones. Based on this reasonable expectation of success, a person of ordinary skill in the art would be motivated to administer the food bar of US '606 to treat and reduce the risk of kidney stones.

The references do not specifically teach using the wheat germ in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient in the food bar composition to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Double Patenting

12. Applicant is advised that should claims 9-10 be found allowable, claims 13-16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

13. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The

examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.

Susan D. Coe
2/22/05

Susan D. Coe
Primary Examiner
Art Unit 1654